REMARKS

Claims 1-68, 81, 87, and 89 remain pending in this application.

In an Office Communication dated February 15, 2005, the Examiner indicated that the Amendment filed on October 18, 2004 was not fully responsive, stating:

> Applicants state that they address Obvious-Type Double Patenting Rejection (ODP) in response to 35 U.S.C. §103 rejection. However, there is nothing in the response to 35 U.S.C. § 103 rejection that addresses the issue of ODP, namely that the claims of the instant application are obvious variants of already patented claims."

In response, Applicants respectfully submit that the Amendment filed on October 18, 2004 was fully responsive to the Office Action. In his April 15, 2004 Office Action, the Examiner rejected claims 1-68, 81, 87 and 89 under Obvious-Type Double patenting in view of U.S. Patent No. 6,248,345. The Examiner also issued a § 103(a) rejection over these same claims in view of the '345 patent. According to the MPEP, chapter 804, '[a] double patenting rejection of the obviousness-type is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103" except that the patent principally underlying the double patenting rejection is not considered prior art. In re Braithwaite, 379 F.2d 594, 154 U.S.P.Q. 29 (CCPA 1967). Therefore, the analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. § 103 obviousness determination. In re Braat, 937 F.2d 589, 19 U.S.P.Q2d 1289 (Fed.Cir. 1991); In re Longi, 759 F.2d 887, 225 U.S.P.Q. 645 (Fed.Cir. 1985). As the arguments presented on page 33 of the Amendment to overcome the 35 U.S.C. § 103(a) rejection are appropriate to overcome the Obvious-Type Double Patenting Rejection , Applicants stated on page 19 of the Amendment, their belief that the "claimed invention is patentable over the '345 patent, as explained below."

Notwithstanding, for purposes of clarity, Applicants explain that claims 1-68, 81, 87 and 89 are patentable over claims 1-38 of U.S. Patent No. 6,248,345.

Independent claims 1, 33, 35, 81 and 89 are all directed to the provision of local analgesia, local anesthesia or nerve blockade in a human. In contrast, the only in-vivo data reported in the Goldenheim '335 and '345 patents is for animals. As neither the '335 nor '345 Goldenheim patents provide Cmax or Tmax data for administration of the disclosed formulations to a human being, it cannot be assumed that the formulations of either the '335 or the '345 patents could achieve in a human, the Cmax, Tmax, onset of local analgesia, local anesthesia, nerve blockade, level of local anesthetic at the site of administration, or the duration of action recited in the rejected claims.

Further, even with regard to the administration to animals, the '345 patent does not teach or suggest "the level of bupivacaine at the site of administration [is] at least 150 times the level of bupivacaine in the blood plasma" as recited in independent claim 33 nor does it teach or suggest "wherein the mean Tmax of bupivacaine at the tissue site occurs at a time point from about 10 hours to about 45 hours after first administration" as recited in independent claim 35. Clearly, the formulation described in the '345 patent would not necessarily possess the same pharmacokinetic characteristics or parameters in humans as recited in the claims of the present application[1]

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1 It is worth noting that the doctrine of inherency requires more than "the mere fact that a certain result or characteristic may occur or be present in the prior art". MPEP, 8th edition, Revision 2, section 2112, citing In re Rijckaert, 9 F.3d 1531, 1534, 28 U.S.P.Q. 2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); In re Oelrich, 666 F.2d 578, 581-82, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981). This issue is discussed in detail in Applicants' October 18, 2004 Amendment.

It is respectfully requested that the rejection of claims 1-68, 81, 87 and 89 under Obvious-Type Double patenting in view of U.S. Patent No. 6,248,345 be withdrawn.

As a separate issue, Applicants point out that a corresponding PCT application to cited U.S. Patent No. 6,248,345 published on January 14, 1999, before the filing date of the present application. Therefore, Applicants cannot file a terminal disclaimer to overcome this rejection.

CONCLUSION

Applicants respectfully request that the Examiner remove the pending rejection of claims 1-68, 81, 87 and 89 under Obvious-Type Double patenting in view of U.S. Patent No. 6,248,345.

An early and favorable action is earnestly solicited.

Respectfully submitted,
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